REMARKS

The Final Office Action mailed February 26, 2010, has been carefully studied. The claims in the application are now claims 1-5, 7-15 and 19-31. These claims define not only novel and unobvious subject matter as the PTO apparently agrees, but these claims also meet all the requirements of 35 USC §112. Favorable reconsideration of the Final Rejection and allowance are accordingly respectfully requested.

First, claims 16-18 are cancelled above. This is the only amendment made above. It was intended that these claims be cancelled in the last Reply as indicated in the penultimate paragraph of the Reply filed December 1, 2009, but this inadvertently was not done. Applicants respectfully reiterate that such cancellation is made without prejudice to Applicants' rights to pursue these and/or similar claims in a continuing application without any penalty whatsoever, if Applicants choose to do so.

The previous prior art rejection has been withdrawn, whereby Applicants understand that Applicants' claims are deemed by the PTO to define novel and unobvious subject matter under §§102 and 103.

Claims 1-5 and 7-31 have been again rejected under the first paragraph of 35 USC §112. As understood from the Final Action, however, instead of the rejection now being based on lack of enablement (particularly the process of making) as raised in the preceding Office Action, the rejection is now

based on the "written description" requirement because Applicants have not shown that they had possession of the claimed invention at the time the application was filed (page 4 of the Final Action). The rejection is respectfully traversed whether it is based on alleged lack of enablement or alleged lack of written description, and for the reasons as set forth in the preceding Reply, respectfully repeated by reference, as well as the additional reasons given below.

In more detail, and as best understood, the Examiner's position is as follows:

As particularly stated, the instantly claimed compounds are salts in which R^2 is selected from the claimed variables and not hydrogen. As such, while guidance is present in the application for making compounds wherein R^2 is H, there is no guidance (according to the rejection) in the specification for making compounds wherein R^2 is as instantly claimed. However, the issue in this case is whether the applicant had possession of the claimed compounds at the time of the instant application. The Declaration, pages 8-9, describes 'step v' that adequately provides for a method for converting a compound in which R^2 is hydrogen to the claimed compound (R^2 = Na, etc). This critical step 'step v' however is missing in the specification (see page 16)… Given that the 'metes and bounds' of the invention is based on the R_2 groups of the instant compounds, the question is: whether the above-mentioned 'step v' used for making these 'novel' R^2 groups, was completed before the filing date of the instant application.

As indicated above, it seems to Applicants that the rejection is based on alleged lack of "written description,",

but mixed up with such rejection it appears that the Examiner maintains lack of enablement arguments.

The subject matter examined in this case pertains to compounds and compositions of formula (I) in claim 1, wherein R^3 and R^4 are H, and R^1 and R^2 being the variables as instantly claimed, i.e., R^1 is a C_8-C_{18} acyl group, an amino acid group or a C_1-C_{17} alkyl group; and R^2 is ammonium, a monovalent metal cation of Na^+ or K^+, a divalent alkaline earth metal cation of Mg^{2+}, Ca^{2+} or Ba^{2+}, or a trivalent metal cation of Al^{3+} or Fe^{3+}.

Insofar as the rejection still contains elements of the lack of enablement rejection previously made, Applicants believe that such rejection is fully rebutted in the preceding Reply and in the Declaration of Dr. Belakhov, previously filed, particularly relating to "step v".

In particular,

(i) According to the process described in the specification: (i) the 5′ and 6′ hydroxyl groups of ascorbic acid are protected with a ketone of the general formula R^7R^8CO, wherein R^7 and R^8, the same or different, each is C_1-C_{10} alkyl; (ii) the protected ascorbic acid obtained in step (i) is reacted with a compound of the general formula R^1Hal, wherein R^1 is as defined in claim 1, e.g., a C_8-C_{18} acyl group; (iii) the compound obtained in step (ii) is reacted with a concentrated carbonate solution of the metal R^2, wherein R^2 is as defined in claim 1; and (iv) the compound obtained in step (iii) is then hydrolyzed to deprotect the 5′ and 6′ hydroxyl groups thus obtaining the desired product, i.e., a compound of the general formula (I) in claim 1, wherein R^3 and R^4 are both hydrogen.

(ii) According to the process described in Dr. Belakhov's declaration, steps (i) and (ii) are identical to those of the specification;

(iii) The compound obtained in step (ii) is hydrolyzed to deprotect the 5' and 6' hydroxyl groups; and the compound obtained in step (iii) is then reacted with a concentrated carbonate solution of the metal R^2 so as to obtain the desired product. This process is indeed slightly different than that described in the specification in that the deprotection of the 5- and 6-hydroxyl groups is performed prior to [*and not after*] the reaction with the carbonate solution of the metal R^2.

(iii) Nevertheless, it is definitely clear that the change introduced to the process for the preparation of the compounds of the present invention, as reflected by the description in Dr. Belakhov's declaration and explained above, is well within the capabilities of any person skilled in the art, as it is supported by common knowledge available at the time the present application was filed, and therefore may be expected from any person skilled in the art. In fact, conversion of an ascorbic acid derivative, in which the hydrogen of the 2' hydroxyl is substituted, to the salty form thereof, i.e., to such a derivative in which the hydrogen of the 3' hydroxyl is substituted with a metal ion, in particular lithium, is described in EP 0619313, cited in the International Search Report issued for the parent PCT application and in the Office Action of October 22, 2008.

Furthermore, conversion of an ascorbic acid derivative, in which the hydrogen of the 2' hydroxyl only is substituted, to the salty form thereof will in most cases lead

to the substitution of the hydrogen of the 3' hydroxyl, since it is well known to any person skilled in the art that the 3' hydroxyl is the most acidic hydroxyl (pK_a 4.25) of ascorbic acid, which is generally a weak organic acid (see page 35, Table 3.1, in Davies M.B., Austin J. and Partridge D.A., "Vitamin C. Its Chemistry and Biochemistry, Cambridge: Published by Royal Society of Chemistry", **1991**, chapter 3, 26-47. (A copy of that chapter was attached to the last Reply.) Therefore, this hydroxyl will be the first hydroxyl to react with the carbonate solution of the metal R^2 to obtain compound I, wherein R^3 and R^4 are each hydrogen.

On page 5 of the Final Action, the Examiner focuses on the time of possession of the invention. Applicants do not see how the time of possession of the invention can be an issue with respect to the "written description" requirement in the present case. As to the "enablement" requirement, "time" would only be an issue if those skilled in the art did not know how to carry out "step v" at the time the present invention was made. But it has been shown that those skilled in the art would have known how to carry out "step v" at the time the present invention was made.

The present application as filed evidences that Applicants had possession of the present invention at the time the present application was filed, and the written description requirement is fulfilled by the evidence of the text of the present application itself. This appears repeatedly in Applicants' specification as filed. For example, the Abstract states that R^2 "is ammonium or a metal cation;…." The Summary section of Applicants' specification at page 7, lines 11 and 12,

states that "R^2 is ammonium or a metal cation;…." This is repeated and amplified at page 8, lines 5-11. Also see the original claims which provide their own support, and thus provide evidence of satisfaction of the written description requirement.

Section 2163 of the MPEP provides guidelines for the Examination of patent applications under the "Written Description" requirement of the first paragraph of 35 USC §112. The burden for maintaining such a rejection is on the PTO, and is very substantial. Thus, MPEP 2163 II.A. states in part as follow:

> The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. **There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed,…** [citation omitted; emphasis added].

Why would it be doubted that the Applicants did not possess the subject matter described in the specification and called for in the claims as filed? There is no reason.

MPEP 2163 II.A.3(a), "Original claims," further states in part:

> An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. [citations omitted; emphasis added].

Can there be any doubt that Applicants' original claims do not call for the subject matter in question? Of course not!

Applicants believe and respectfully submit that there is absolutely no question whatsoever with respect to the written description requirement, as the written description exists in Applicants' specification as filed. As regards enablement, the Examiner previously raised the issue, and it was rebutted in the preceding Reply, as further indicated above.

Withdrawal of the rejection is in order and is respectfully requested.

Favorable reconsideration of the §112 rejection, withdrawal of such rejection and allowance of the claims are in order and are respectfully requested.

Respectfully submitted,

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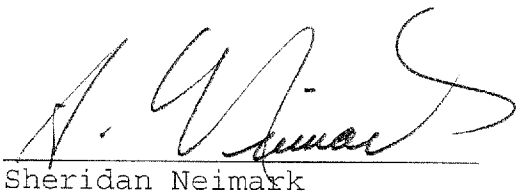
By 
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